

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

ST. JUDE MEDICAL AB
Patent Dept.
S-175 84 Järfälla
SUÈDE

Date of mailing (day/month/year) 30 November 2000 (30.11.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 99 P 2008 P	
International application No. PCT/SE00/01073	International filing date (day/month/year) 25 May 2000 (25.05.00)

1. The following indications appeared on record concerning:		
<input checked="" type="checkbox"/> the applicant	<input type="checkbox"/> the inventor	<input type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address PACESETTER AB S-175 84 Järfälla Sweden	State of Nationality SE	State of Residence SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input type="checkbox"/> the person	<input checked="" type="checkbox"/> the name	<input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence
Name and Address St. JUDE MEDICAL AB S-175 84 Järfälla Sweden	State of Nationality SE	State of Residence SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
<input checked="" type="checkbox"/> the receiving Office	<input checked="" type="checkbox"/> the designated Offices concerned	
<input type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned	
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Marie-José Devillard Telephone No.: (41-22) 338.83.38
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REC'D 24 JUL 2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

2



Applicant's or agent's file reference 99 P 2008 P	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE00/01073	International filing date (day/month/year) 25/05/2000	Priority date (day/month/year) 28/05/1999
International Patent Classification (IPC) or national classification and IPC A61N1/365		
Applicant St.JUDE MEDICAL AB		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 14/11/2000	Date of completion of this report 20. 07. 01
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Schoeffmann, H Telephone No. +49 89 2399 2625 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/SE00/01073

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, pages:

1-10 as received on 11/06/2001 with letter of 08/06/2001

Claims, No.:

1-6 as received on 11/06/2001 with letter of 08/06/2001

Drawings, sheets:

1/2,2/2 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/SE00/01073

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-6
	No: Claims
Inventive step (IS)	Yes: Claims 1-6
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-6
	No: Claims

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/SE00/01073

I.

1. The amendments filed with the letter dated 8.6.01 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following: in claim 4, PAC (premature atrial contraction) has been introduced for which no basis can be found in the application documents as filed, nor has a basis been indicated by the applicant.

V.

1. The invention relates to an implantable heart stimulator which has means for safe detection and distinction of heart signals (QRS, PVC, T) and for determining the origin of the detected signals. Devices of that kind are known from eg. EP-A-0 917 887 (D1) which discloses the features of the preamble of claim 1. The claimed device has the advantage that signals need to be detected in only one chamber of the heart so that the stimulator is more easily implantable. This object is achieved by the features of the characterising clause of claim 1, ie. in substance by splitting the signal from one sensing electrode into at least two channels and applying different bandpass filtering whereby the channels are continuously active.

According to D1, signals detected between the atrial and ventricular electrode and between the ventricular electrode and the stimulator housing are analysed. In the stimulator according to EP-A-0 646 390 (D2) signals are detected between the atrial and ventricular electrode in order to distinguish between signals with different origins in the heart.

Claim 1 is thus considered to meet the requirements of Art.33 PCT as do claims 2-6 dependent thereon.

(19) World Intellectual Property Organization
International Bureau



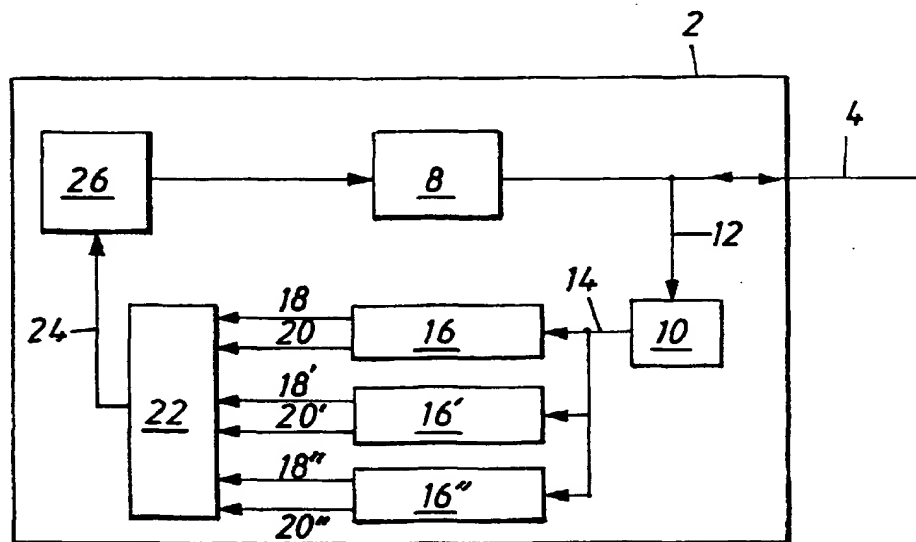
(43) International Publication Date
7 December 2000 (07.12.2000)

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(10) International Publication Number
WO 00/72916 A1

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- (21) International Application Number: PCT/SE00/01073
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9901966-3 28 May 1999 (28.05.1999) SE
- (71) Applicant (for all designated States except US): PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).
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- OBEL, Martin [SE/SE]; Bergavägen 5, S-182 33 Danderyd (SE).
- (74) Common Representative: PACESETTER AB; Patent Dept., S-175 84 Järfälla (SE).
- (81) Designated State (national): US.
- (84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- Published:
— With international search report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPLANTABLE HEART STIMULATOR



(57) Abstract: Implantable heart stimulator comprising a heart signal detection means (10) adapted to detect electrical heart signals (12) and to apply said signals to at least two detection channels (16, 16', 16''), each channel comprises a filter means with a predetermined filter characteristics, a threshold detector with a predetermined threshold and a peak amplitude determining means. Each channel is adapted to generate a detection signal and a peak amplitude value. The heart stimulator further comprises a heart event identifying means (22) that unequivocally identifies, based on said detection signals and said peak amplitude values, a detected heart event. Applying predetermined identifying criteria, e.g. by forming the difference and/or the quote between the peak amplitude values performs said identification.

Implantable heart stimulatorTechnical field of the invention

- 5 The present invention relates to an implantable heart stimulator, e.g. a pacemaker or a defibrillator, according to the preamble of the independent claim.

Background of the invention

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The purpose of the invention is to improve the detection safety of a heart signal detection means in an implantable heart stimulator.

- 15 In conventional pacemaker technology often a single band-pass filter is used in the sensing circuit of the pacemaker in order to detect electrical heart signals. When using this known technique the origin of a signal that caused a sensed event is difficult to determine.

- 20 A ventricular event occurring early in the heart cycle (prior a normally timed QRS-complex) and arising from a focus in the ventricles is often referred to as a premature ventricular contraction (PVC).

- 25 If a PVC not is detected due to undersensing it can result in that inappropriately timed, asynchronous or competitive stimulation pulses are delivered. Undersensing is defined as a failure of the pacemaker to sense an electrical signal related to a heart event, e.g. a PVC, due to that the sensitivity of the sensing circuit of the pacemaker is too
30 low. This can often be corrected by programming the pacemaker to a more sensitive setting, i.e. decreasing the value of the sensitivity level.

- 35 US-4,880,004 discloses an implantable cardiac stimulator for detecting and treating cardiac arrhythmias. The stimulator includes a sense amplifier responsive to sensed cardiac signals for detecting and distinguishing normal and abnormal

cardiac activity within the sensed signals. The sense amplifier includes an automatic gain control amplifier, a filter and a comparator having a pair of signal channels for processing the sensed signals according to different

5 frequency bandpass characteristics to establish sensing thresholds, margins and signal gain. One of the signal channels constitutes a feedback loop for determining the signal gain and the sensing margin for the other channel.

10 In US-5,350,402 an atrial defibrillator is disclosed including a first detector for detecting R-waves of the heart and a second detector for detecting T-waves of the heart. The detection criterion is based on a predetermined time interval relationship between the R-wave and the T-
15 wave. According to a software implementation of the T-wave detector a microprocessor may be implemented for filtering the output of a sense amplifier with a high-pass filter and a low-pass filter. The derivative of the filtered signal is calculated using a discrete differentiation of the filtered
20 data and re-filtered with a low-pass filter. These values are used in further calculations to determine if a T-wave is detected.

In US-5,755,739 an adaptive and morphological system for
25 discriminating P-Waves and R-waves inside the human body is disclosed. A drawback of a system using morphological recognition is that it probably not is fast enough for real time operation and that it is often implemented by a microprocessor that has unacceptable high energy
30 consumption.

In US-4,305,396 an improved automatically rate adaptive pacemaker is disclosed. The theory behind this patent is that a correlation has been identified between e.g. the
35 amplitudes of the R-wave and T-wave and the heart rate. This correlation is then used to control a rate-responsive pacemaker. The peak values of the QRS-wave and T-wave,

respectively, are detected in detection windows using conventional techniques. The detected values are then applied to a correlation block where a rate-controlling signal is generated.

5

One object of the present invention is to improve the safety in detecting electrical heart signals and to make it possible to determine the origin of detected signals. The heart stimulator according to the invention is in particular useful for a safe detection of premature ventricular contractions (PVCs).

10

Another object of the invention is to arrange an implantable heart stimulator having a detection of electrical heart signals that is fast and low energy consuming.

15

Short description of the inventive concept

The above objects are achieved by the invention in accordance with the characterizing portion of the appended main claim. Preferred embodiments are set forth in the dependent claims.

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Short description of the appended drawings

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Figure 1 shows an implantable heart stimulator. Figure 2 shows a block diagram of the implantable heart stimulating device according to the invention. Figure 3 shows a block diagram of a detection channel according to the invention. Figure 4 shows a block diagram of a preferred embodiment of a part of a detection channel according to the invention.

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Detailed description of preferred embodiments of the invention

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Figure 1 discloses an implantable heart stimulator comprising a heart stimulating device 2 and an electrode lead 4 inserted into the ventricle of a heart 6. The electrode lead is inserted into the heart and arranged in the ventricle according to procedures well known to persons skilled in the art. The heart stimulator disclosed in Fig. 1 relates to a single chamber heart stimulator, which means that the electrode lead is arranged in one chamber of the heart, in this case the right ventricle. However, it should be noted, that the invention is equally applicable in a dual chamber heart stimulator that comprises two heart electrode leads adapted to stimulate the heart both in the atrium and in the ventricle and also in a multi-chamber heart stimulator adapted to stimulate three or four chambers of the heart.

Figure 2 discloses the implantable heart stimulating device 2 according to the invention that comprises a pulse generator 8 for generating heart stimulating pulses to the heart via electrode lead 4. The heart stimulating device 2 further comprises a heart signal detecting means 10 connected to the electrode lead 4 and adapted to receive electrical heart signals 12 and to generate detected electrical heart signals 14 to three detection channels 16, 16', 16''. Each channel is adapted to generate a detection signal 18, 18', 18'' and a peak amplitude value 20, 20', 20'' to a heart event identifying means 22 that generates a signal 24 that identifies a detected heart event and applies said signal to a control means 26.

30

Figure 3 discloses one of the detection channels 16. The detection channel 16 comprises a filter means 28 that generates a filtered signal 30 that is applied to a threshold detector 32 and to a peak amplitude determining means 34. If the filtered signal exceeds a predetermined threshold 36 of said threshold detector 32 the detection

35

signal 18 is generated. The peak amplitude determining means 34 generates said peak amplitude value 20.

The invention is described in relation to a single chamber heart stimulator, i.e. with one electrode lead placed in the atrium or in the ventricle of the heart. As mentioned above the invention is equally applicable in a dual chamber heart stimulator where, for each electrode lead, a heart signal detection means and at least two detection channels are associated.

Each filter means 28 has a predetermined filter characteristics, that differs from that of a filter means in another detection channel.

If the heart signal detection means 10 receives signals detected in the ventricle of the heart, the predetermined filter characteristics of the filter means in three parallel detection channels are e.g. tuned to be sensitive to R-waves, T-waves and PVCs, respectively.

The filter means sensitive to R-waves is a band-pass filter with a pass-band in the range 20-50 Hz.
The filter means sensitive to T-waves is a band-pass filter with a pass-band in the range 2-10 Hz.
And the filter means sensitive to PVCs is a band-pass filter with a pass-band typically in the range 15-40 Hz.

If the heart signal detection means 10 instead receives signals detected in the atrium of the heart, the predetermined filter characteristics of the filter means in two parallel detection channels preferably are tuned to be sensitive to P-waves and far-field R-waves, respectively.
The filter means sensitive to P-waves is a band-pass filter with a narrow pass-band around 30 Hz.
The filter means sensitive to far-field R-waves is a band-pass filter with a pass-band typically in the range 10-35 Hz.

It is however possible to arrange further detection channels both for detection in the atrium and in the ventricle. E.g. to be able to detect different kinds of arrhythmia, states of atrial or ventricular fibrillation etc.

5

The filter means can be implemented using digital or analog filter techniques.

If a digital filter is used the analog detected heart signal is A/D converted before filtration is performed and the processing of the filtered signal in the threshold detector and in the peak amplitude determining means is digital.

If an analog filter instead is used the above-mentioned processing might also be performed in an analog threshold detector and in an analog peak amplitude determining means. As an alternative the filtered signal is A/D-converted after the filtration and then applied to the threshold detector and the peak amplitude determining means.

The filter characteristics discussed above could either be set at the manufacture of the implantable device or could be set by a physician during implantation of the device or later at a follow-up visit. The filter means could be automatically tuned by tuning means in the heart event identifying means.

Figure 4 discloses a preferred embodiment of the threshold detector 32 and the peak amplitude determining means 34. The filtered signal 30 comprises a stream of digital bits representing the heart signal. The bit-stream is applied to the threshold detector 32 which is a digital comparator with a threshold 36 that generates the detection signal 18 if the filtered signal exceeds said threshold. The detection signal is applied to the peak amplitude determining means 34 that, according to this embodiment, is a shift register. When a detection signal is received by the determining means 34, the digital bit-stream is clocked into the shift register

during a predetermined time, about 10 - 30 ms. When the predetermined time has elapsed, the content of the shift register is inspected in order to find the maximum value and that value is then generated as the peak amplitude value 20.

5

According to another preferred embodiment of the invention the heart signal detection means receives signals detected in the ventricle of the heart. In figure 2 the detection channel 16 is tuned to be sensitive to R-waves, the
10 detection channel 16' is tuned to be sensitive to T-waves and the detection channel 16'' is tuned to be sensitive to PVCs. The detection channel 16 generates detection signal 18 (R_{det}), indicating a detected R-Wave, and a peak amplitude value 20 (R_{max}) indicating the peak amplitude of the detected
15 R-wave. According to the same principles T_{det} , T_{max} , PVC_{det} and PVC_{max} are generated by the detection channels 16', 16'', respectively.

The detection signals and the peak amplitude values are
20 received by the heart event identifying means 22 where a number of heart event identifying criteria are applied.

To unequivocally identify an R-wave the following criteria must be fulfilled:

25 Detection signal R_{det} received, i.e. no T_{det} or PVC_{det} , and $R_{max}/PVC_{max} > 1$ (also $R_{max}/T_{max} > 1$ could be checked).
The division R_{max}/PVC_{max} need only be performed if there also was a PVC_{det} .
 $R_{max} - PVC_{max} > 0$ can be used instead of $R_{max}/PVC_{max} > 1$.

30

To unequivocally identify a PVC the following criteria must be fulfilled:

Detection signal PVC_{det} received, i.e. no R_{det} or T_{det} and $PVC_{max}/R_{max} > 1$ and $PVC_{max}/T_{max} > 1$ if PVC_{det} and R_{det} .
35 The division PVC_{max}/R_{max} need only be performed if there also was an R_{det} .
 $PVC_{max} - R_{max} > 0$ can be used instead of $PVC_{max}/R_{max} > 1$.

Typical values for R_{\max} is in the range of 6-12 mV and for PVC_{\max} is in the range of 3-6 mV. T_{\max} has a maximal peak amplitude below 1 mV.

- 5 According to a second preferred embodiment of the invention the heart signal detection means receives signals detected in the atrium of the heart. In figure 2 only two detection channels are used and the detection channel 16 is tuned to be sensitive to P-waves and the detection channel 16' is
10 tuned to be sensitive to far field R-waves. The detection channel 16 generates detection signal 18 (P_{\det}), indicating a detected P-Wave, and a peak amplitude value 20 (P_{\max}) indicating the peak amplitude of the detected P-wave. According to the same principles $R(\text{far-field})_{\det}$ and $R(\text{far-field})_{\max}$
15 are generated by the detection channel 16'.

To unequivocally identify a P-wave the following criteria must be fulfilled:

- 20 Detection signal P_{\det} received and $P_{\max}/R(\text{far-field})_{\max} > 1$ if P_{\det} and $R(\text{far-field})_{\det}$.

To unequivocally identify a far-field R-wave the following criteria must be fulfilled:

- 25 Detection signal $R(\text{far-field})_{\det}$ received and $R(\text{far-field})_{\max}/P_{\max} > 1$ if $R(\text{far-field})_{\det}$ and P_{\det} .

Typical values for P_{\max} when filtered with the P-wave adapted filter is in the range of 3-4 mV and when filtered with the far-field R-wave adapted filter in the range of 2-3 mV.

- 30 Typical values for $R(\text{far-field})_{\max}$ when filtered with the P-wave adapted filter is in the range of 2-3 mV and when filtered with the far-field R-wave adapted filter in the range of 3-4 mV.

- 35 It should be noted that the individual variability regarding signal amplitudes may be significant.

The heart event identifying means 22 is implemented either by software in a microprocessor or by a digital network using commonly available programming technique or digital network design, respectively.

5

The filter means are continuously active which means that each filter means in each of the detection channels receives detected electrical heart signals and performs filtration during the whole heart cycle.

10

As soon as a detection signal is received by the heart event identifying means the peak amplitude values received during a predetermined time interval, e.g. from 0 to 30 ms, are used in the above-mentioned identifying criteria to identify the detected heart event.

15

The signal 24 identifying a detected heart event is applied to the control means 26 where appropriate action is taken in response of the detected heart event. That could be the reset of certain time intervals, the change of mode of operation for the heart stimulator and the adjustment of certain parameters, e.g. the sensitivity level. All this actions are well known to a person skilled in the art of heart stimulators and therefore not further described in the present application.

20

According to still another embodiment of the invention the heart event identifying means 22 is provided with means for tuning and adjusting the filter means to be more sensitive to the heart event it is intended to detect, e.g. R-waves.

25

That could be done by e.g. changing the band-width or another filter parameter of the filter.

30

In the embodiments of the invention described above the heart signal detection technique is only briefly discussed.

It should be noted that any detection technique resulting in a detection of heart signals is applicable in the present invention. The heart signal can be detected by a single

bipolar electrode lead by measuring between a tip and a ring electrode surfaces. If instead a unipolar heart electrode is used detection is performed between a tip electrode surface and an electrode surface at the pacemaker housing. Still
5 another possibility is to detect between electrode surfaces at different electrode leads that could be unipolar, bipolar or multipolar. The above-mentioned measurement techniques and expressions are well known to a person skilled in the art of heart stimulators and are therefore not further
10 described.

The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above
15 embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.

Claims

1. Implantable heart stimulator comprising a heart signal detection means adapted to detect electrical heart signals and to apply said signals to at least two detection channels (16,16',16''), each channel comprises a filter means (28) with a predetermined filter characteristic, a threshold detector (32) with a predetermined threshold (36) and a peak amplitude determining means (34), wherein said filter means generates a filtered signal (30) that is applied to said threshold detector that generates a detection signal (18,18',18'') if said filtered signal exceeds said threshold and to said peak amplitude determining means that generates a peak amplitude value (20,20',20'') of said filtered signal **characterized in** that said heart stimulator further comprises a heart event identifying means (22) that unequivocally identifies, based on detection signals and peak amplitude values from different detection channels, a detected heart event.
2. Implantable heart stimulator according to claim 1 **characterized in** that said channels are continuously active.
3. Implantable heart stimulator according to any preceding claim **characterized in** that said identification is performed by applying predetermined heart event identifying criteria.
4. Implantable heart stimulator according to claim 3 **characterized in** that said identifying criteria include forming the quote and/or the difference between peak amplitude values provided that at least one detection signal is received by the heart event identifying means.
5. Implantable heart stimulator according to any preceding claim **characterized in** that said predetermined filter characteristics for filter means in different detection channels are tuned to be sensitive to R-waves, T-waves and

PVCs, respectively.

6. Implantable heart stimulator according to any of claims 1-4 **characterized in** that said predetermined filter characteristics for filter means in different detection channels are tuned to be sensitive to P-waves and far-field R-waves, respectively.
7. Implantable heart stimulator according to any preceding claim **characterized in** that said heart event identifying means comprises tuning means adapted to tune said filter means.
8. Implantable heart stimulator according to any preceding claim **characterized in** that said detected heart event could be any of the following: an R-wave, a T-wave, a PVC, a P-wave or a far-field R-wave.

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Fig. 1

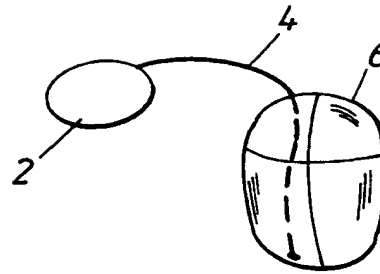
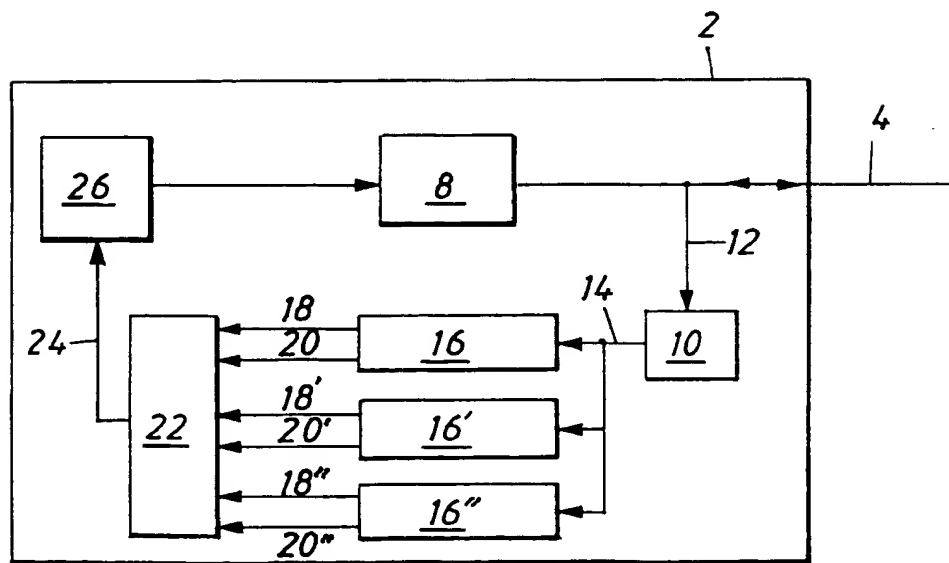


Fig. 2



2 / 2

Fig. 3

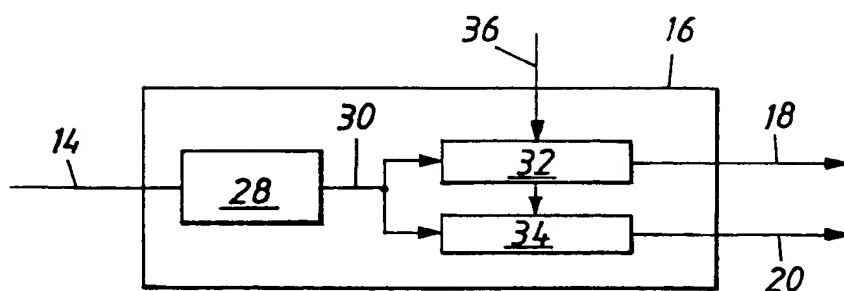
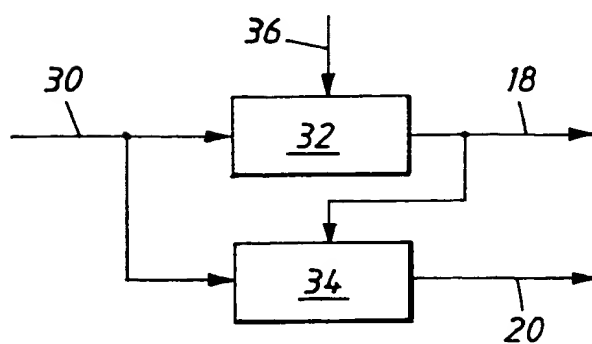


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01073

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365, A61B 5/0402

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0917887 A1 (PACESETTER AB), 26 May 1999 (26.05.99), column 3, line 17 - line 30; column 5, line 5 - line 11; column 10, line 16 - line 19, column 11, line 57 - column 12, line 30 --	1-8
A	EP 0646390 A1 (PACESETTER AB), 5 April 1995 (05.04.95), abstract --	1-8
D,A	US 4880004 A (R.G. BAKER, JR. ET AL.), 14 November 1989 (14.11.89), abstract --	1-8
D,A	US 5350402 A (K.R. INFINGER ET AL.), 27 Sept 1994 (27.09.94), abstract --	1-8

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

- * Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

11 Sept 2000

Date of mailing of the international search report

18 -09- 2000

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International application No.

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